ATTACHMENT B

REMARKS

By the present amendment, Claims 1, 7, 9 and 15 have been amended in a manner as suggested by the Examiner to clearly show that these claims are directed to subject matter that is not disclosed or suggested in the prior art. In light of the present amendments, the application overcomes all prior rejections and has been placed in condition for allowance for the reasons as set forth below.

The present invention as exemplified in amended Claims 1 and 9 and the claims dependent therefrom is directed to an antibody which is capable of binding to the specific M31 subregion of the collagen binding domain of the collagen binding protein of *Staphylococcus aureus*,[1] and this antibody has not previously been disclosed or suggested in any prior art reference. As set forth in Applicants' specification, e.g., at Example 5.6, subsection 5.6.1 at page 106, the specific M31 subregion has the sequence of amino acids 61-343 of the full length collagen binding protein, said full length protein having been known and referred to in the specification as having GenBank Accession number M81736. The full length sequence was also shown in the Patti et al. 1992 Journal of Biological Chemistry article cited by the Examiner in the previous action, but this article does **not** disclose or suggest the generation of antibodies to the specific M31 subregion, as explained further below.

In the Final Rejection, there was only one remaining objection, namely a rejection of the Claims under 35 U.S.C. §102(b) on the basis of the Patti et al. 1992 Journal of Biological Chemistry article which referred entirely to the full length collagen binding

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[1]Applicants have adopted the claim language format as set forth in the USPTO Written Description Guidelines for claims directed to antibodies (see Example 16, "Antibodies", pages 59-60, attached hereto).

protein of *S. aureus* and an antibody generated thereto, but which did not disclose or suggest antibodies to any specific subregion of the collagen binding domain of said protein. In the Official Action, the Examiner appeared to recognize that the present invention was directed to an antibody that was not disclosed or suggested in the prior 1992 Patti reference, namely one that related to an antibody capable of recognizing a specific subregion of the collagen binding domain of the collagen binding protein, but argued that the previous language of the claims did not appear to be limited to antibodies recognizing specific subregions of the collagen binding domain of the collagen binding protein and thus could not be distinguished from the prior art antibody to the full length collagen binding protein.

Without addressing the arguments concerning the scope of the claims as they stand prior to the entry of the present amendments, Applicants have now overcome the Examiner's rejection by amending the claims to point out that the present invention is in fact directed to antibodies capable of binding to a specific subregion of the collagen binding domain of the collagen binding protein, namely that region which has been identified as region M31 and which has the amino acid sequence of amino acids 61-343 of the full length collagen binding protein as identified in Applicants' specification. As such, the present invention is clearly not disclosed or suggested by the prior Patti 1992 reference which merely discloses the full length collagen binding protein and an antibody raised thereto, and clearly does not disclose or suggest an antibody capable of binding to any specific subregion of the collagen binding protein of *S. aureus,* much less the one specifically claimed in the present application. Indeed, antibodies directed to the full length protein are different than antibodies directed to a specific subregion, as has been pointed out in the prior response in the Declaration of Dr. Patti filed therewith.

It is thus clear that the claims as presently amended are directed to an antibody that is clearly not disclosed or suggested in the prior art Patti reference, and the Examiner's prior rejections of the claims, insofar as applied to the claims as amended, are respectfully traversed and should be withdrawn.

In light of the amendments and arguments as set forth above, Applicants respectfully submit that upon entrance of the present amendments, the present application will be placed in condition for allowance, and thus entrance of the amendment and allowance of this case is earnestly solicited.

END OF REMARKS

SYNOPSIS OF APPLICATION OF WRITTEN DESCRIPTION GUIDELINES

Contents

Example 16: Antibodies

Specification: The specification teaches that antigen X has been isolated and is useful for detection of HIV infections. The specification teaches antigen X as purified by gel filtration and provides characterization of the antigen as having a molecular weight of 55 KD. The specification also provides a clear protocol by which antigen X was isolated. The specification contemplates but does not teach in an example antibodies which specifically bind to antigen X and asserts that these antibodies can be used in immunoassays to detect HIV. The general knowledge in the art is such that antibodies are structurally well characterized. It is well known that all mammals produce antibodies and they exist in five isotypes, IgM, IgG, IgD, IgA and IgE. Antibodies contain an effector portion which is the constant region and a variable region that contains the antigen binding sites in the form of complementarity determining regions and the framework regions. The sequences of constant regions as well as the variable regions subgroups (framework regions) from a variety of species are known and published in the art. It is also well known that antibodies can be made against virtually any protein.

→ **Claim:** An isolated antibody capable of binding to antigen X.

Analysis:

A review of the full content of the specification indicates that antibodies which bind to antigen X are essential to the operation of the claimed invention. The level of skill and knowledge in the art of antibodies at the time of filing was such that production of antibodies against a well-

characterized antigen was conventional. This is a mature technology where the level of skill is high and advanced.

The claim is directed to any antibody which is capable of binding to antigen X.

A search of the prior art indicates that antigen X is novel and unobvious.

Considering the routine art-recognized method of making antibodies to fully characterized antigens, the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature, one of skill in the art would have recognized that the spectrum of antibodies which bind to antigen X were implicitly disclosed as a result of the isolation of antigen X.

→ **Conclusion:** The disclosure meets the requirement under 35 USC 112 first paragraph as providing an adequate written description of the claimed invention.